Axcis™ PMR Delivery System
Part of the Eclipse PMR System
Catalog Number _____

Information for Use

Caution: Federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner). Federal law further restricts the use of this device to practitioners who have been trained in laser interventional cardiology including laser operation.

Caution: Use of this device is restricted to patients who have signed a procedure-specific consent form to ensure that the risks associated with PMR have been fully explained and understood.

CE **0086**

Do not reuse

Sterile-EtO

Read Instructions

1. DEVICE DESCRIPTION

The Eclipse PMR System is composed of the New Star Holmium:YAG laser, the ECG monitor and the Axcis? PMR Delivery System. The laser radiation emitted from this system has a wavelength of approximately 2.1 microns, which is in the mid-infrared (invisible) range of the electromagnetic spectrum. Water is the target absorber for this laser wavelength. This laser emits 350 microsecond laser radiation pulses at a 35 millisecond pulse repetition interval. The energy output from the laser aperture is 2.7 Joules while the clinical level is 2 Joules per pulse. The pulses are synchronized with the cardiac cycle through the ECG monitor which provides a trigger signal to allow synchronization of the heartbeat with the delivery of laser energy. There is a visible laser beam used for calibration.

The laser energy is delivered to the target tissue via an optical fiber. The Axcis PMR Delivery System is a single-use, coaxial assembly composed of two catheters—an outer Aligning Catheter and an inner Laser Catheter. The Axcis Aligning Catheter is available in several tip configurations (See Section 10, How Supplied). The System also includes an Introducer Tool, which is used to insert the Laser Catheter into the Aligning Catheter.

2. INDICATIONS FOR USE

The Eclipse PMR System is indicated for use in percutaneous myocardial revascularization (PMR) procedures to decrease angina and increase exercise tolerance in patients with chronic angina (Canadian Cardiovascular Society Angina Scale Class III or IV) which is refractory to medical treatment and

secondary to objectively demonstrated coronary artery disease and with a region of the myocardium with reversible ischemia not amenable to direct coronary revascularization.

3. CONTRAINDICATIONS

No contraindications known.

4. WARNINGS AND PRECAUTIONS

- The Axcis PMR Delivery System may only be used with an Eclipse PMR laser.

Explosion or fire hazard

- Do not operate the laser in the presence of flammable substances, including gases, anesthetics, cleaning agents, combustible materials, or other volatile substances. **Explosions or fire can result**.
- Combustible or flammable materials (e.g. drapes, gowns or gauze) may be ignited by laser radiation unless they are kept wet or moistened.
- Surround the procedure field with wet towels or wet gauze.
- Modify all other flammable materials to make them fire-retardant (e.g. flame resistant drapes or gowns). Minimize oxygen exposure as oxygen increases the combustibility of materials exposed to laser radiation.

Laser radiation The laser is classified as a Class IV laser product as defined in the Code of Federal Regulations (21 CFR 1040.10(b)].

- Avoid exposure to laser radiation at all times during the installation and operation of the laser as direct or reflected radiation may damage skin or eyes.
- DO NOT LOOK DIRECTLY INTO THE LASER BEAM since permanent ocular damage may result.
- Protect the patient's eyes by covering them with wet gauze or protective eyewear.
- All catheterization laboratory personnel must wear protective eyewear with a minimum optical density of 3 at a wavelength of 2.1 ?m when the laser is in use.

Physician Training

- The Eclipse PMR System should only be used by properly trained cardiologists (see Section 11.3 Operator Training).

Handling and Sterilization of Axcis PMR Delivery System

- The Laser Catheter and Aligning Catheter are sterilized with EtO gas and are **for single-use only. Do not re-sterilize or reuse.**
- The Introducer Tool is reusable and can be cleaned and re-sterilized. (see Section 11.2).
- Inspect the sealed sterile package before opening. Product is sterile only in unopened, undamaged package. If the package is opened or damaged, or if the seal is broken, the contents may not be sterile and may cause infection in the patient.
- Do not bend the fiberoptic at sharp angles. The Axcis Laser Catheter should not be bent beyond a bend radius of 7 mm.

Biohazard After use, handle and dispose of the Laser and Aligning Catheters as appropriate for a biohazard.

Precautions during PMR

- The wall thickness in the targeted region should be assessed prior to the PMR procedure using echocardiography. PMR should not be performed in areas of the myocardium that are:
  - Less than 8 mm in wall thickness
  - Infarcted
  - In the region of the mitral valve or mitral valve apparatus
  - In the region of the papillary muscle
  - In the region of a left ventricular mural thrombus
- ? Subjects with pre-existing right bundle branch block are at higher risk of developing a complete heart block. Subjects with this pre-existing condition should not be treated in the septal area. Either a temporary pacemaker may be placed at the time of the PMR procedure or the proper equipment for the rapid insertion of a temporary pacemaker should be available.
- PMR should only be performed under fluoroscopic observation and care must be taken not to duplicate channel locations. Firing the laser into a previously formed channel may cause perforation.
- The Axcis PMR Delivery System consists of devices that are delicate and must be manipulated carefully.
- The Axcis Aligning Catheter is stiffer than standard PTCA guiding catheters and can potentially place significant force on the heart wall. Care must be taken not to bend or wedge the optical fiber by pushing the lens too vigorously against the endocardium. The laser should never be fired under these conditions.
- Do not fire the laser when the lens is retracted within the Aligning Catheter. Retract the lens before repositioning the Laser Catheter.
- If the Axcis PMR Delivery system does not move freely, the catheters may be wedged within the left ventricle or the lens may be entrapped within trabeculae or the chordae tendinae. In this case, the Laser Catheter and lens should be withdrawn into the Aligning Catheter. The Aligning Catheter should then be withdrawn into a position that frees the device.
- The Aligning Catheter may be used for manual contrast injections using a syringe only. The Aligning Catheter should not be used with a power injector. The Laser Catheter should not be used for contrast injection.
- If the patient experiences ventricular fibrillation during the procedure, discontinue the procedure and treat the arrhythmia as appropriate. A defibrillator should be readily available at all times during the procedure.

5. ADVERSE EFFECTS

5.1 Observed Adverse Events

The "PACIFIC" randomized trial of PMR using the Eclipse PMR System plus medical management (PMR+MEDs) versus medical management alone (MEDs) enrolled 200 patients who were followed for a total of 185.6 patient-years.

There were no intra-procedural deaths in the study. Within 30 days of treatment, one PMR+MEDs patient died of cardiac causes. During 12 months follow-up an additional 6 PMR+MEDs patients died (5 from cardiac causes and 1 from respiratory arrest) and 2 patients in the MEDs group died (both due to cardiac causes).

A summary of all serious adverse events in the PACIFIC study is given in **Table 1**.

Table 1: Serious Adverse Events

Includes all adverse events, both related and unrelated to PMR, sorted by system affected.

	PMR+MEDs (n=100)		MEDs (n=100)	
Event[1]	**Patients with Event**	**Number of Events**	**Patients with Event**	**Number of Events**
All CV events combined	50	108	48	103
Angina	25	49	39	74
Arrhythmias[2]	11	12	4	6
Death (all causes)	7	7	2	2
Heart Failure	8	8	2	2
Injury to heart structure (perforation)	3	3	0	0
Myocardial infarction	11	12	5	8
Other cardiovascular[3]	16	18	7	9
Thromboembolic disorder	4	4	2	3
All DER Events Combined	1	1	2	3
All GU Events Combined	2	2	2	2
All GEN Events Combined	10	11	7	7
All GI Events Combined	8	12	3	4
All NEU Events Combined	3	4	1	1
All PSY Events Combined	2	2	1	2
All RES Events Combined	7	10	3	4
All AE Combined	56	159	52	130

[1]Abbreviations: CV = cardiovascular, DER = dermatologic, GEN = general, GI = gastrointestinal, GU = genitourinary, HEM = hematologic, LAB = laboratory, MET = metabolic, MUS = musculoskeletal, NEU = neurologic, PSY = psychiatric, RES = respiratory, AE = adverse events.

[2]Arrhythmias (number of patients with each in treatment/control groups) were: arrhythmia (0/2), ventricular arrhythmia (1/0), AV block complete (1/0), bradycardia (4/1), atrial fibrillation (2/0), atrial flutter (2/0), heart block (1/0), tachycardia (0/1).

[3]Other cardiovascular events (number of patients with each in treatment/control groups) were: heart arrest (4/0), syncope (2/2), vascular disease peripheral (3/2), amblyopia (0/1), vascular anomaly (1/0), cellulitis (1/0), creatine PK increase (1/0), pericardial effusion (1/0), embolism (1/0), hypotension (1/0), artery occlusion (0/1), carotid occlusion (0/1), coronary stenosis (1/0), ulcer (1/0).

5.2 Potential Adverse Events

Possible adverse effects include but are not limited to the following:

- death
- myocardial perforation which can lead to tamponade
- abnormalities of cardiac function (myocardial infarction, left ventricular dysfunction, heart failure, cardiogenic shock, arrhythmias)
- thromboembolic disorders and stroke
- respiratory failure
- arterial dissection
- infection
- inadvertent injury to structures of the heart
- inadvertent injury to structures outside of the heart
- fragmented catheters and lens tips
- vascular damage

6. CLINICAL STUDY

Purpose: The purpose of this study was to compare PMR and medical management (PMR + MEDs) to medical management alone (MEDs). **Primary outcome measures** were angina classification and exercise tolerance; quality of life was a secondary outcome measure and safety measures were mortality and adverse events.

Design and Patients: This multi-center, prospective, randomized controlled trial was conducted at 11 U.S. centers with 200 patients studied between November 1997 and August 1999; 100 randomized to PMR and 100 randomized to MEDs. There were 17 withdrawals and 9 deaths. The remaining 174 patients reached one year follow-up. Baseline characteristics and cardiac risk factors were similar between the two groups.

Methods: PMR was performed using standard percutaneous techniques via the femoral artery through a 9F or 10F introducer sheath. The Axcis PMR Delivery System catheters were advanced into the left ventricle. Channels were created from the endocardium approximately 5 mm into the myocardium. All channel placement was guided by fluoroscopy.

Results: **Table 2** lists the principal safety and effectiveness results. There were statistically significant differences in angina improvement and exercise tolerance (defined as total duration of exercise testing).

Table 2: Principal Safety and Effectiveness Results

All patients in the Randomized Trial (n=200)	PMR+MEDs (n=100)	MEDs (n=100)	P-value
Angina Improvement			
Success	42.0% (n=42)	8.0% (n=8)	<0.001
Failure	58.0% (n=58)	92.0% (n=92)	
12-Month Angina Distribution			0.001
None	0.0% (n=0)	1.0% (n=1)	
Class I	29.0% (n=29)	4.0% (n=4)	
Class II	35.0% (n=35)	11.0% (n=11)	
Class III	14.0% (n=14)	44.0% (n=44)	
Class IV	15.0% (n=15)	38.0% (n=38)	
Mortality			
<30 days	1.0% (1)	0% (0)	0.170
≥30 days	6.0% (6)	2% (2)	
Exercise Tolerance Improvement	50.8 (n=99)	-6.4 (n=97)	0.014
Quality of Life Improvement			
Physical Limitation Scale	12.3 (n=95)	0.4 (n=95)	<0.001
Anginal Stability Scale	26.0 (n=96)	4.2 (n=96)	<0.001
Anginal Frequency Scale	19.3 (n=95)	7.1 (n=97)	<0.003
Treatment Satisfaction Score	9.4 (n=96)	1.7 (n=97)	<0.001
Disease Perception Score	28.5 (n=96)	9.1 (n=97)	<0.001

Angina Improvement: Success was defined as improvement of 2 or more CCSAS classes from baseline to 12 months.

12-Month Angina Distribution: Distribution of angina at 12 months by CCSAS class as assessed by the Clinical Investigator at each site.

Mortality: Proportionate analysis p = 0.170 by 2-Tail Fisher's Exact Test and 0.089 by Kaplan Meier Analysis, Log Rank Test.

Exercise Tolerance Improvement: Improvement in exercise duration in seconds from baseline to 12 months.

Quality of Life Improvement: Seattle Angina Questionnaire analysis scores improvement from baseline to 12 months. Higher scores indicate higher quality of life.

7. PATIENT SELECTION AND TREATMENT

Specific Patient Populations

The safety and effectiveness of the Eclipse PMR System has not been established for the following specific populations:

- patients under the age of 18;
- patients who are pregnant or undergoing labor and delivery or are nursing mothers;
- patients suffering from active hepatic disease, renal failure, cancer or major infection;
- patients with a left ventricular ejection fraction less than 30%;
- patients with CCSAS class II or better angina;
- patients with myocardial ischemia limited to the right ventricular wall.

8. PATIENT COUNSELING INFORMATION

This device is restricted to use in patients who sign a procedure-specific informed consent to ensure that the risks associated with PMR have been fully explained to, and understood by, the patient.

Patients should be advised that any reduction of angina may occur gradually, that they should continue on their anti-anginal medications, and that the need for these medications will be re-evaluated at subsequent visits.

Patients should be advised of the risks of the procedure including the possibility of:

- recurrence of angina;
- progression of myocardial ischemia;
- worsening heart failure;
- cardiac arrhythmia;
- death

9. CONFORMANCE TO STANDARDS

The Eclipse PMR System laser conforms with the requirements of the following domestic and international standards:

- IEC601-1:1988 Medical Electrical Equipment, General Requirements for Safety
- IEC60601-1-2:1993 Medical Electrical Equipment, General Requirements for Safety, Collateral: Electromagnetic
- IEC601-2-22: 1992 Medical Electrical Equipment, Particular Requirements for the Safety of Diagnostic and Therapeutic Laser Equipment.
- 21CFR Part 1040.10 Laser Product Performance Standard

The ECG monitor meets the requirements of:

- EN55011, Group I, Class A 1991 Conducted Emissions and Radiated Emissions
- EN 61000-4-2, 1995-01 Electrostatic Discharge Immunity
- EN 61000-4-3 1995-02 Radiated Electromagnetic Immunity
- EN 6100-4-4 1995-01 Electrical Fast Transient/Burst Immunity
- EN 50141 1994 Conducted Disturbance Induced by RF Fields

10. HOW SUPPLIED

10.1 PACKAGING

The Eclipse PMR System consists of the New Star laser, the ECG monitor, the disposable Axcis PMR Delivery System (Axcis Laser Catheter, Axcis Aligning Catheter) and the Introducer Tool.

? ? The laser and ECG monitor are initially installed in the hospital by Eclipse personnel.

- The single-use delivery system is supplied sterile and non-pyrogenic. Sterility may be compromised if the package is opened or damaged. Do not re-sterilize the Axcis Laser or Aligning Catheters.
- The Introducer Tool may be re-used if desired and must be cleaned and sterilized according to the procedures outlined in this document. (see Section 11.2)

10.2 Storage

All fiberoptic delivery system catheters should be stored under conditions that protect against extremes of temperature and humidity. Products should be stored in a clean, dry environment, protected from water. Do not stack other objects on packaging to avoid crushing. Proper stock rotation should be practiced. Store in a cool, dry area. Do not expose to organic solvents, ionizing radiation or ultraviolet light.

10.3 Axcis PMR Delivery System

Axcis Aligning Catheter:	Ultra-1, Ultra-1 Long, Ultra-2, Ultra-3 and Open-2 configurations to reach various cardiac anatomies
Axcis Laser Catheter:	fiberoptic which delivers laser energy
Introducer Tool	tool used to insert the Laser Catheter into the Aligning Catheter
SMA Cleaning Kit	lint-free swabs and pre-moistened pads to clean the laser fiberoptic receptacle

10.4 Materials Required for Use (Not Provided)

- 9F introducer sheath for femoral artery access
- 5F or 6F introducer sheath for contralateral femoral artery access (optional)
- 7F or 8F introducer sheath for femoral vein access
- appropriately shaped angiographic catheter(s)
- 0.035-inch. or 0.038-inch guide wire
- 6F angiographic pigtail catheter, 125 cm long
- right-heart catheter for measurement of pulmonary artery pressures (optional)
- pressure transducers (2)
- pressure bags with infusion line sets including 3-way stopcocks (2)
- Heparinized saline, 1,000 U/liter or per standard practice, 500 ml bags (2)
- 2D echo
- pericardiocentesis set
- plastic transparency film for marking of channel locations on fluoro monitors

11. CLINICIAN USE INFORMATION

11.1 Patient Informed Consent

In addition to the standard consent form, Eclipse requires a procedure-specific consent form to be signed by each patient to ensure that the risks associated with PMR have been fully explained to the patient.

11.2 Device Operating Instruction

INSPECTION PRIOR TO USE

Prior to the procedure, carefully inspect all equipment to ensure that no component of the Axcis PMR Delivery System has been fractured or damaged. If there is any damage to a component or its packaging, the component should not be used. Any damaged component should be returned to Eclipse Surgical Technologies, Inc.

Note the location of the stainless steel Introducer Tool within the Laser Catheter pouch. Care should be taken to preserve sterility during removal of the Introducer Tool from the pouch.

PRE PROCEDURE PREPARATION

1. Ensure that everyone in the room is wearing laser safety goggles.
2. Attach the power cord to an appropriate power outlet.
3. Clean the laser fiberoptic receptacle. Carefully clean the inner surface of the fiberoptic receptacle using a lint-free cleaning swab. Upon removal of the cleaning swab from the laser, inspect the swab for dust or debris. Repeat this procedure using new cleaning swabs until the swab comes away from the laser free of visible signs of dust or debris. To avoid possible damage to the laser optics, do not insert the cleaning swab more than 2 cm into the fiberoptic receptacle.

   Carefully clean the outer surface of the fiber receptacle using a pre-moistened cleaning pad. Inspect the cleaning pad for dust or debris. Repeat this procedure using new cleaning pads until the pad comes away from the laser clean and free of visible signs of dust or debris.
4. Place electrodes on the patient's right arm, left arm, and left leg. Attach the leads to the electrodes on the patient and connect the cable to the front of the ECG monitor. Attach the ECG monitor to the laser. See the Eclipse PMR Holmium Laser System User Manual for instructions.
5. Turn on the ECG monitor and the laser. Test the function of the laser prior to patient preparation. See the Eclipse PMR Holmium Laser System User Manual for instructions.
6. At this point, femoral and venous (optional) access should be secured. Use 9F or 10 F for the Axcis PMR system, 5F or 6F on the contralateral femoral artery [optional] and 7F or 8F for the femoral vein(optional).
7. Introduce a diagnostic coronary catheter through the smaller femoral sheath. Place a 6F pigtail and guidewire.
8. Introduce the Aligning Catheter through the appropriate femoral sheath. Introduce the Aligning Catheter over a 6F pigtail catheter and a guidewire into the left ventricle.
9. For fluoroscopy, isocenter should be determined prior to proceeding to the next step and should be maintained throughout the procedure.

10. Acquire orthogonal fluoro projections optimized for the targeted region; record coronary and ventricular angiograms.
11. The Aligning Catheter should be advanced over the pigtail into the apical region in preparation for the introduction of the Laser Catheter.
12. **Once working projections have been established at this point, the TABLE SHOULD NOT BE MOVED.** Moving the table will result in an inability to accurately localize channels relative to the cardiac anatomy.

PREPARATION OF THE LASER CATHETER:

Note: The following steps are to be performed by both a scrubbed-in assistant, for catheter preparation, and a non-scrubbed-in laser operator.

13. Using standard sterile technique, remove the Laser Catheter from the pouch.
14. Remove the Introducer Tool and place it in the sterile field for later use. Remove the Laser Catheter from the package.
15. Transfer the proximal SMA laser connector to the non-sterile person who will operate the laser. The laser operator should then remove the protective cap.
16. Insert the connector into the laser. It is extremely important that this step be performed slowly and carefully. The following steps should be taken to insure that the Laser Catheter is successfully attached to the laser:
    - The cylindrical portion of the connector must be inserted very slowly and carefully into the laser receptacle. The face of the connector, which contains the optical fiber, must not be brought into contact with the laser receptacle. The connector must then be slowly inserted using gentle force that is directed straight into the receptacle. No binding or drag should occur as the connector is inserted. Binding or drag indicates that the connector is not being inserted straight into the receptacle.
    - Once fully seated, the nut should be fully tightened onto the receptacle.

CLINICAL USE

17. Test the Axcis Laser Catheter as follows:
    - Partially fill a small basin with sterile water.
    - While wearing laser safety glasses, place laser in READY mode.
    - Place the distal end of the optical fiber into the basin, such that the lens is submerged in water and 1-2 cm from the side or bottom of the basin. Depress the laser footswitch. Energy from the fiber should cause the water to vaporize with a snapping sound; there should be no error code displayed on the laser. If a distinct snapping sound is not heard when the laser fires, or if white flashing at the lens is noted when the laser fires, do not use the catheter for the procedure. Prior to attaching a new catheter to the laser, clean the laser fiber receptacle per the instructions in step 3 above.

ATTACHMENT AND ADJUSTMENT OF HEPARINIZED SALINE DRIP LINES:

18. Fully advance the fiber so that 7-8 cm are extended.
19. Flush both the proximal and distal sideports with saline and attach drip lines with stopcocks closed. Drip lines should be attached to two individual pressure bags pressurized to 300 mm Hg and filled with heparinized saline.
20. Open the stopcocks and adjust for appropriate drip rate. Close the stopcocks.
21. Place the Laser Catheter onto the sterile field. It is now prepared for introduction through the Aligning Catheter.
22. Place a piece of plastic transparency film over the fluoro screen and trace the major coronary arteries and other anatomical landmarks. Record the angulation and tilt of the projection on the transparency. Do this for both projections that will be used during channel creation. From this point forward, these projections must be used in order to maintain the ability to accurately localize channels.

INTRODUCING THE LASER CATHETER:

23. **Visually inspect the Introducer to ensure that the Introducer is undamaged and that the slot width is uniform**. Insert the fiber into the slot of the Introducer.
24. Holding the fiber and catheter tip, slowly retract the lens into the Introducer. Verify that the petals fold into the Introducer without catching on the edge. **Do not force the lens into the Introducer. Discard any Introducer that presents excessive resistance to the insertion of the lens.**
25. Open the stopcocks on both of the heparinized saline drip lines.
26. Insert the Introducer into the hub of the Aligning Catheter. Insert the Laser Catheter into the Aligning Catheter.
27. When the lens is fully within the Aligning Catheter, remove the Introducer. Maintain sterility of the Introducer since it may be needed again.
28. Once the shaped tip of the Laser Catheter is 5-10 cm into the Aligning Catheter, slide the distal sidearm forward and attach to the Aligning Catheter. Exercise care to not draw the Aligning Catheter out of the ventricle.
29. Fully retract the fiber and advance the Laser Catheter until the radiopaque lens marker is seen in the most distal segment of the Aligning Catheter. At that point, the Laser Catheter should not be advanced further but should be held in position as the Aligning Catheter is retracted in an “unsheathing” motion.
30. At this point the trigger delay should be adjusted to end-systole according to the instructions in the laser User Manual. The trigger point is indicated by the bright spot on the ECG tracing. The trigger point should be

monitored periodically throughout the procedure and adjusted as required to maintain an end-systolic triggering point.

MANIPULATING THE AXCIS PMR DELIVERY SYSTEM

31. Once the catheters are in the left ventricle, the user can manipulate them by any of the following adjustments to target the various regions of the heart:
    (a) advancement/retraction of the entire system *en bloc*
    (b) rotation of the Aligning Catheter
    (c) advancement/retraction of the Laser Catheter with the Aligning Catheter held stationary
    (d) rotation of the Laser Catheter with the Aligning Catheter held stationary
    (e) advancement/retraction of the optical fiber/lens with the Laser and Aligning Catheters held stationary

DO NOT TORQUE THE LASER CATHETER WHEN THE SHAPED TIP IS WITHIN THE ALIGNING CATHETER DO NOT EXTEND OR RETRACT THE LENS WHEN THE LASER CATHETER TIP IS WITHIN THE ALIGNING CATHETER

32. Using these adjustments, various catheter configurations are possible, including the following:
    (a) "C" configuration, in which the curves of both catheters lie in the same plane and point in the same direction
    (b) "S" configuration, in which the curves of both catheters lie in the same plane but point in opposite directions
    (c) "MP" (multiplane) configuration, in which the curves of both catheters lie in orthogonal planes

    It may be useful to orient the tip of the Aligning Catheter toward the apex and then target specific regions by rotating and/or advancing/retracting the Laser Catheter with the Aligning Catheter held in a stable position. Rotational control of the Laser Catheter is accomplished by rotation of the tapered nose cone located on the proximal controller assembly.
33. Configurations that permit only slight extension of the lens from the Laser Catheter and the Laser Catheter from the Aligning Catheter should be avoided, since they will cause potentially dangerous loading of the lens against the endocardium.
34. Using these adjustments and configurations, position the Axcis PMR System so that the lens is aimed at the targeted region. Then confirm the position of the device by fluoroscopy, using projections that provide orthogonal views.
35. Once the appropriate position has been confirmed, the lens should be moved toward the endocardium by slowly advancing the fiber handle located on the proximal controller assembly.

36. Contact with the myocardial wall is usually indicated by fluoroscopic visualization of the catheter "backing away" from the wall, as well as by a change in the motion of the radiopaque marker located on the distal-mounted lens: it will change from a slight reciprocating movement to a noticeable beating motion when it comes in contact with the beating heart. Initial contact is also commonly indicated by the occurrence of premature ventricular contractions (extrasystoles). IT IS IMPORTANT THAT THE FIBER NOT BE SQUEEZED OR WEDGED AGAINST THE ENDOCARDIUM, AS EVIDENCED BY SEVERE FLEXING.

CREATING CHANNELS

NOTE: The laser should not be fired with the lens positioned in an infarct region. The laser should not be fired with the lens positioned in the region of the mitral valve or the mitral valve apparatus.

37. Place the laser in READY mode by pressing the READY button on the laser control panel.
38. With the laser in READY mode, depress the foot switch. The laser will fire a burst of pulses equal to the pulse preset setting on the laser control panel.

    Note: Channels may be formed using either one or two bursts of laser energy, each burst typically consists of two pulses. If a second burst is desired, proceed with the following step; otherwise omit the following step.
39. Following very slight additional advancement of the optical fiber (approximately 1 mm), fire a second burst by depressing the foot switch. Two bursts of two pulses per burst are customarily fired for each channel attempt in a region with wall thickness of 8 mm or greater.
40. Mark the channel location on the transparencies in both orthogonal views.
41. After marking the channel location, retract the fiber to its fully-retracted position and reposition for the next channel. Channels should be spaced approximately 1 cm apart.
42. Repeat this sequence for the desired number of channels.
43. With the optical fiber fully retracted, remove the Laser Catheter by withdrawing it through the Aligning Catheter.
44. Ventriculography should be performed in at least two optimized planes.
45. Remove the Aligning Catheter by withdrawing it through the femoral sheath.
46. Removal of the access sheaths and subsequent achievement of hemostasis should be performed according to standard practice.

47. Reuse of the Introducer Tool:

Pre-Cleaning (Introducer Tool only)

The Introducer Tool should be rinsed thoroughly using lukewarm water (below 43° C / 110° F) immediately following use.

Cleaning (Introducer Tool only)

The Introducer Tool should be cleaned following each procedure using a low-sudsing, protein-dissolving detergent or a combination of an enzymatic cleaner followed by a manual detergent. Follow the manufacturer's instructions regarding concentration, temperature, contact time and reuse. Clean using a soft-bristle brush. Do not soak in hot water, alcohol, disinfectants or antiseptics to avoid coagulation of blood or other body fluids. Do not use steel wool, wire brushes or abrasive detergents.

Rinse thoroughly with water to remove all traces of debris or cleansing agents. **Inspect the Introducer Tool to ensure that it is undamaged and that the slot width is uniform.**

STERILIZATION (Introducer Tool only)

The Introducer Tool should be sterilized in a gravity-displacement steam-sterilization cycle of 15 minutes at a minimum of 132° C (270° F) or a pre-vacuum steam-sterilization cycle of 4 minutes at a minimum of 132° C (270° F).

11.3 Operator Training

Federal law restricts the use of this device to practitioners who have been trained in laser cardiology intervention techniques including laser operation. Operator training for use of the Eclipse PMR System must include training in the use of the laser and the fiberoptic delivery system, as well as appropriate clinical training.

Laser Training:

The American National Standards Institute offers the following Standard of Practice for the Use of Lasers in Medicine and Surgery:

ANSI Z136.3 "American National Standard for Safe Use of Lasers in Health Care Facilities", 1996.

Clinical Training:

Use of the Eclipse PMR System should only be undertaken by personnel who have met the standards of the Eclipse continuing education training program, which includes didactic and hands-on-training covering:

- Patient selection
- Percutaneous myocardial revascularization technique
- Patient management.

Further information about training can be obtained form an Eclipse Surgical Technologies, Inc. representative at 800-238-2205.

12. PATIENT'S MANUAL

The brochure "Information for Patients considering Percutaneous Myocardial Revascularization (PMR)" provides general information to the potential patient regarding the risks and benefits associated with PMR treatment.

13. PRODUCT INFORMATION DISCLOSURE

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